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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,215

04/08/2005

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KAMADA1

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1444 7590 05/19/2009  
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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

05/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,215	<b>Applicant(s)</b> KAMADA ET AL.	
	<b>Examiner</b> Elli Peselev	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-11, 16-18, 25-28 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11, 16-18, 25-28 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Miura et al (U.S. Patent No. 5,959,088).

Applicant's arguments filed March 17, 2009 have been fully considered but they are not persuasive.

Applicant contends that claims 28 and 35 are directed to Crystal Form D, which crystal is obtained from Crystal Form E and which possess superior properties, including reduced content of residual solvent and a larger particle size. This argument has not been found persuasive. The Hiraide et al (US 2003/0191296 A1) state in paragraph [0040] that the D-type crystal prepared via the E-type crystal ensures a residual solvent content of 1500 ppm or below, which could not be achieved by the prior art D-type crystal and in paragraph [0042], state that the D-type crystal with a large average particle size cannot be obtained by the prior art process. However, Hiraide et al do not provide a comparison of the residual solvent content and particle size of the claimed Form D and the Form D disclosed by Miura et al. Further, the stability testing of crystal form D disclosed by Miura in Figures 7 and 8 teaches that Crystal Form D was known in the art at the time of the claimed invention.

Claims 8-11, 25-28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miura et al (U.S. Patent No. 5,959,088) in view of Spanton et al (U.S. Patent No. 5,945,405).

The compound claims are directed to form G-crystals, which are solvates. In paragraph [0071] of the specification it is stated that crystal forms G are solvates of crystal form D (G1 is an acetone solvate, G2 is a methylethylketone solvate and G3 is a tetrahydrofuran solvate). Miura et al disclose form D crystals of hemifumarate erythromycin derivative (see, for example, Figures 7 and 8). Spanton et al disclose tetrahydrofuran solvates of an erythromycin derivative. It would have been prima facie

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obvious to a person having ordinary skill in the art at the time the claimed invention was made to prepare solvates of the compound disclosed by Miura et al according to the processes disclosed by Spanton et al since preparation of solvates of erythromycin compounds was well known in the art as disclosed by Spanton et al.

Applicant's arguments filed March 17, 2009 have been fully considered but they are not persuasive.

Applicant contends that claimed Crystal Forms G are novel crystalline forms and Miura neither explains nor describes the Crystal Form D hydrates as a starting material. This argument has not been found persuasive. The claimed crystalline Form are seen nothing more than solvates of a crystalline form disclosed by Miura. Since the preparation of solvates of analogous compounds was well known in the art as disclosed by Spanton et al, the claimed compounds and their process of preparation are still deemed prima facie obvious over the cited prior art.

Claims 16-18, 23, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miura et al in view of Spanton et al as applied to claims 8-11, 25-28 and 35 above, and further in view of Bosch et al (U.S. Patent No. 6,504,017).

Miura et al disclose a humifumarate crystal of an erythromycin derivative. Spanton et al discloses various solvates of erythromycin crystals but does not disclose drying said solvates under reduced pressure. However, since Bosch et al disclose a conventional process for drying erythromycin solvates under reduced pressure (column 3, lines 60-67 and column 4, line 1), it would have been prima facie obvious to a person

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having ordinary skill in the art at the time the claimed invention was made to use the conventional drying method disclosed by Bosch et al for drying solvates encompassed by the present claims..

Applicant's arguments filed March 17, 2009 have been fully considered but they are not persuasive.

Applicant contends that Crystal Forms G are not obvious over Miura. This argument has not been found persuasive for the reasons set forth above. With respect to the conditioning step, which reads on drying, note that drying of solvates was well known in the art at the time the claimed invention was made as disclosed by Bosch.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev  
/Elli Peselev/  
Primary Examiner, Art Unit 1623